

S/N 10/537,963

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	CHAN ET AL.	Examiner:	UNKNOWN
Serial No.:	10/537,963	Group Art Unit:	3643
Filed:	MARCH 9, 2006	Docket No.:	11669.150USW1
Confirmation No.:	1445	Customer No.:	23552
Title:	TRANSGENIC MICE EXPRESSING HUMAN CD20 AND/OR CD16		

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
(37 C.F.R. § 1.97(b))

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner.

This statement should be considered because it is submitted before the mailing date of a first Office Action on-the-merits. Accordingly, no fee is due for consideration of the items listed on the enclosed Form 1449.

In accordance with 37 C.F.R. §1.98(a)(2), a copy of each document or other information listed on the enclosed Form 1449 is provided.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

MERCHANT & GOULD P.C.  
P.O. Box 2903  
Minneapolis, Minnesota 55402-0903  
(612) 332-5300

Date: August 7, 2006

*Katherine M. Kowalchyk*  
Katherine M. Kowalchyk  
Reg. No. 36,848

**23552**

PATENT TRADEMARK OFFICE

<b>FORM 1449*</b> <b>INFORMATION DISCLOSURE STATEMENT</b> <b>IN AN APPLICATION</b> (Use several sheets if necessary)			Docket Number: 11669.150USW1	Application Number: 10/537,963
			Applicant: CHAN ET AL.	
			Filing Date: March 9, 2006	Group Art Unit: 3643

<b>U.S. PATENT DOCUMENTS</b>						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
<b>FOREIGN PATENT DOCUMENTS</b>						
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
	I 452 093	09/01/1994	EP			YES      NO
	WO 02/062946 A2	08/15/2002	PCT			
<b>OTHER DOCUMENTS</b> (Including Author, Title, Date, Pertinent Pages, Etc.)						
	Arzoo et al., "Treatment of refractory antibody mediated autoimmune disorders with an anti-CD20 monoclonal antibody (rituximab)", <u>Ann. Rheum. Dis.</u> , 61:922-924 (2002)					
	Butler, "The Amplified ELISA: Principles of and Applications for the Comparative Quantitation of Class and Subclass Antibodies and the Distribution of Antibodies and Antigens in Biochemical Separates", <u>Methods in Enzymology</u> , 73:482-523 (1981)					
	Capecchi, "Altering the Genome by Homologous Recombination", <u>Science</u> , 244:1288-1292 (1989)					
	Capecchi, "The New Mouse Genetics: Altering the Genome by Gene Targeting", <u>TIG</u> , 5(3):70-76 (1989)					
	Davis et al., "Single-Agent Monoclonal Antibody Efficacy in Bulky Non-Hodgkin's Lymphoma: Results of a Phase II Trial of Rituximab", <u>Journal of Clinical Oncology</u> , 17(6):1851-1857 (1999)					
	Fleit et al., "A Soluble Form of Fc $\gamma$ RIII is Present in Human Serum and Other Body Fluids and is Elevated at Sites of Inflammation", <u>Blood</u> , 79(10):2721-2728 (1992)					
	Foran et al., "European Phase II Study of Rituximab (Chimeric Anti-CD20 Monoclonal Antibody) for Patients with Newly Diagnosed Mantle-Cell Lymphoma and Previously Treated Mantle-Cell Lymphoma, Immunocytoma, and Small B-Cell Lymphocytic Lymphoma", <u>Journal of Clinical Oncology</u> , 18(2):317-324 (2000)					
	Gong et al., "Importance of cellular microenvironment and circulatory dynamics in B cell immunotherapy", <u>Journal of Immunology</u> , 174(2):817-826 (2005)					
	Gopal et al., "Clinical applications of anti-CD20 antibodies", <u>J. Lab. Clin. Med.</u> , 134:445-450 (1999)					
	Kim et al., "Construction and Characterization of a Human Bacterial Artificial Chromosome Library", <u>Genomics</u> , 34:213-218 (1996)					
	Mansour et al., "Disruption of the proto-oncogene <i>int-2</i> in mouse embryo-derived stem cells: a general strategy for targeting mutations to non-selectable genes", <u>Nature</u> , 336:348-352 (1988)					
	Mathiot et al., "Correlation Between Soluble Serum CD16 (sCD16) Levels and Disease Stage in Patients with Multiple Myeloma", <u>Journal of Clinical Immunology</u> , 13(1):41-48 (1993)					
	Polyak et al., "Alanine-170 and Proline-172 are critical determinants for extracellular CD20 epitopes; heterogeneity in the fine specificity of CD20 monoclonal antibodies is defined by additional requirements imposed by both amino acid sequence and					

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.	

<b>FORM 1449*</b> <b>INFORMATION DISCLOSURE STATEMENT</b>		Docket Number: 11669.150USW1	Application Number: 10/537,963
IN AN APPLICATION (Use several sheets if necessary)		Applicant: CHAN ET AL.	
		Filing Date: March 9, 2006	Group Art Unit: 3643

	quaternary structure", <u>Blood</u> , 99(9):3256-3262 (2002)
	Protheroe et al., "Remission of inflammatory arthropathy in association with anti-CD20 therapy for non-Hodgkin's lymphoma", <u>Rheumatology</u> , 38:1150-1152 (1999)
	Shizuya et al., "Cloning and stable maintenance of 300-kilobase-pair fragments of human DNA in <i>Escherichia coli</i> using an F-factor-based vector", <u>Proc. Natl. Acad. Sci. USA</u> , 89:8794-8797 (1992)
	Solal-Celigny et al., "Rituximab as First-Line Treatment of Patients with Follicular Lymphoma (FL) and a Low-Burden Tumor: Clinical and Molecular Evaluation", <u>Blood</u> , 94(10):631a, Abstract #2802 (1999)
	Swiatek et al., "Perinatal lethality and defects in hindbrain development in mice homozygous for a targeted mutation of the zinc finger gene <i>Krox20</i> ", <u>Genes &amp; Development</u> , 7:2071-2084 (1993)
	Trape, "Rituximab chimeric anti-CD20 monoclonal antibody treatment for refractory hemolytic anemia in patients with lymphoproliferative disorders", <u>Haematologica</u> , 88:223-225 (2003)
	Van de Winkel et al., "Human IgG Fc receptor heterogeneity: molecular aspects and clinical implications", <u>Immunology Today</u> , 14(5):215-221 (1993)
	Weiner, "Monoclonal Antibody Therapy of Cancer", <u>Seminars in Oncology</u> , 26(5)(Suppl. 14):43-51 (1999)
	White et al., "Anti-CD20 monoclonal antibodies as novel treatments for non-Hodgkin's lymphoma", <u>Pharm. Sci. Technol. Today</u> , 2(3):95-101 (1999)
	Zelenetz et al., "Iodine I 131 Tositumomab for Patients with Transformed Low-Grade Non-Hodgkin's Lymphoma (NHL): Overall Clinical Trial Experience", <u>Blood</u> , 94(10):632a, Abstract 2806 (1999)
	GenBank Accession No. AH003353 dated February 22, 1996
	GenBank Accession No. BC002807 dated July 15, 2006
	GenBank Accession No. M62541 dated July 26, 1993
	GenBank Accession No. P30273 dated June 13, 2006
	GenBank Accession No. M27394 dated July 15, 1993
	GenBank Accession No. M27395 dated February 22, 1996
	GenBank Accession No. NM_010188 dated June 12, 2006
	GenBank Accession No. NM_000569 dated July 16, 2006
	GenBank Accession No. NM_000570 dated July 2, 2006
	GenBank Accession No. Z46222 dated April 18, 2005
	GenBank Accession No. Z46223 dated March 20, 1997
	Copy of Supplementary Partial European Search Report dated May 22, 2006

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 600; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.	